AUG - 8 2006

Premarket Notification [510(k)] Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is : K060318

Company: Horiba ABX
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Contact Person: Tim Lawton (tlawton@fr.abx.fr)

Date Prepared: 03rd February 2006

Device Names:
The following reagents, controls & calibrators are for use in conjunction with the ABX PENTRA 400, cleared to market under K052007.

REAGENTS :

Trade/Proprietary Name:	**ABX PENTRA AST CP**
Common or Usual Name:	AST – Aspartate amino transferase
Device Class	Class II
Classification Name:	§862.1100 : Aspartate amino transferase (AST/SGOT) Test System
Product Code:	CIT ; NADH oxidation/ NAD reduction, Ast/Sgot

CONTROLS :

Trade/Proprietary Name:	**ABX PENTRA N Control** (K052007)
Common or Usual Name:	N Control
Device Class	Class I
Classification Name:	§862.1660 : Quality control material (assayed and unassayed)
Product Code:	JJY ; Multi-Analyte Controls, All Kinds (Assayed and Unassayed)

Trade/Proprietary Name:	**ABX PENTRA P Control** (K052007)
Common or Usual Name:	P Control
Device Class	Class I
Classification Name:	§862.1660 : Quality control material (assayed and unassayed)

Product Code: JJY ; Multi-Analyte Controls, All Kinds (Assayed and Unassayed)

CALIBRATORS:

Trade/Proprietary Name: **ABX PENTRA Multical** (K052007)
Common or Usual Name: Multical
Device Class Class II
Classification Name: §862.1150 : Calibrator
Product Code: JIX ; Calibrator, Multi-Analyte Mixture

Substantial Equivalence:

The data and information supplied in this submission demonstrates substantial equivalence to their respective predicate devices :

Submission device	Substantially equivalent predicate device
ABX PENTRA AST CP	K801118

Description:

All the reagents, controls and calibrators included in this submission are for use on the **ABX PENTRA 400** (K052007), which is a discrete photometric benchtop clinical chemistry analyzer.

The **ABX PENTRA 400** offers both Closed and Open channels for a multitude of parameters (clinical chemistry, DAT, TDM, plasma protein, hemostasis, optional ISE module).

All reagents described in this submission are for the quantitative in-vitro determination of their respective parameters

Intended Use :

All reagents in this submission are intended for use on the **ABX PENTRA 400** for the quantitative in-vitro determination of AST – Aspartate amino transferase using human serum and plasma.
The controls and calibrators are intended for use in association with the above reagent.

Discussion of Performance Data:

ABX PENTRA AST CP :	
Sample type	Serum & plasma
Detection limit	4 U/l

Accuracy and Precision	CV Total < 4.97%
Measuring range	4 U/l – 600 U/l Automatic post-dilution : 1800 U/l
Correlation (n=103)	Y = 0.99 x + 1.25 with a correlation coefficient r^2 = 0.9963.
Calibration stability	8 days
Reagent stability	closed stability: 15 months at 2-8°C on-board stability (refrigerated area): 55 days

CALIBRATORS

ABX PENTRA Multical:	
Stability	Closed stability: 24 months at 2-8°C Open stability: Once opened, the calibrator components* are stable for : 8 hours at 15°C to 25°C 2 days at 2°C to 8°C 2 weeks at –25°C to –15°C *Exceptions Direct Bilirubin 3 hours at 15°C to 25°C 8 hours at 2°C to 8°C 2 weeks at –25°C to –15°C Total Bilirubin 6 hours at 15°C to 25°C 1 day at 2°C to 8°C 2 weeks at –25°C to –15°C

CONTROLS

ABX PENTRA N Control:	
Stability	Closed stability: 30 months at 2-8°C Open stability: Once opened, the control components* are stable for : 12 hours at 15°C to 25°C 5 days at 2°C to 8°C 1 month at –25°C to –15°C *Exceptions

ABX PENTRA N Control:	
	Direct Bilirubin 4 hours at 15°C to 25°C 8 hours at 2°C to 8°C 2 weeks at –25°C to –15°C Total Bilirubin 8 hours at 15°C to 25°C 1 day at 2°C to 8°C 2 weeks at –25°C to –15°C

ABX PENTRA P Control:	
Stability	Closed stability: 30 months at 2-8°C Open stability: Once opened, the control components* are stable for : 12 hours at 15°C to 25°C 5 days at 2°C to 8°C 1 month at –25°C to –15°C *Exceptions Direct Bilirubin 4 hours at 15°C to 25°C 8 hours at 2°C to 8°C 2 weeks at –25°C to –15°C Total Bilirubin 8 hours at 15°C to 25°C 1 day at 2°C to 8°C 2 weeks at –25°C to –15°C

Conclusions for Performance Testing :
The performance testing data conclude that the safety and effectiveness of the devices are not compromised, and that they met all acceptance criteria, demonstrating that the devices are substantially equivalent to their respective predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Mr. Tim Lawton
Regulatory Affairs Manager
Horiba ABX
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Rue Du Caducee- BP 7290
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France

Re: k060318
Trade/Device Name: Hepatic Enzymes on ABX PENTRA 400
Clinical Chemistry Analyzer
ABX PENTRA Multical
ABX PENTRA N Control
ABX PENTRA P Control
Regulation Number: 21 CFR§ 862.1100
Regulation Name: Aspartate amino transferase (AST/SGOT) test system
Regulatory Class: Class II
Product Code: CIT, JJY, JIX
Dated: June 29, 2006
Received: July 03, 2006

Dear Mr. Lawton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060318

Device Name: Hepatic Enzymes on ABX PENTRA 400 Clinical Chemistry Analyzer

Indications For Use:

Hepatic Enzymes reagents, with associated calibrators and controls, are intended for use on ABX PENTRA 400 Clinical Chemistry Analyzer to measure a variety of analytes.

ABX PENTRA AST CP reagent with associated calibrators and controls are for quantitative in vitro diagnostic determination of aspartate aminotransferase in human serum and plasma based on a UV test using L-aspartate and 2-oxoglutarate. Aspartate aminotransferase measurements are used in the diagnosis and treatment of certain types of liver and heart diseases.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K060318

Indications for Use

510(k) Number (if known): K060318

Device Name: ABX PENTRA Multical

Indications For Use:

The ABX PENTRA Multical is a calibrator for use in the calibration of quantitative Horiba ABX methods on Horiba ABX clinical chemistry analyzers.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K060318

Indications for Use

510(k) Number (if known): K060318

Device Name: ABX PENTRA N Control

Indications For Use:

The ABX PENTRA N Control is for use in quality control by monitoring accuracy and precision.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)

Office of In Vitro Diagnostic Device Evaluation and Safety

(Optional Format 1-2-96) K060318

Indications for Use

510(k) Number (if known): K060318

Device Name: ABX PENTRA P Control

Indications For Use:

The ABX PENTRA P Control is for use in quality control by monitoring accuracy and precision.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Evaluation and Safety

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